

§ 314.90

reason to believe that the reports do not represent actual results obtained.

(d) *Withdrawal of approval.* If an applicant fails to make reports required under this section, FDA may withdraw approval of the application and, thus, prohibit continued marketing of the drug product that is the subject of the application.

(Collection of information requirements approved by the Office of Management and Budget under control number 0910-0001)

[50 FR 7493, Feb. 22, 1985; 50 FR 14212, Apr. 11, 1985, as amended at 50 FR 21238, May 23, 1985; 55 FR 11580, Mar. 29, 1990; 57 FR 17983, Apr. 28, 1992; 63 FR 66670, Dec. 2, 1998; 64 FR 401, Jan. 5, 1999; 65 FR 64617, Oct. 30, 2000; 66 FR 10815, Feb. 20, 2001; 68 FR 69019, Dec. 11, 2003; 69 FR 18766, Apr. 8, 2004; 69 FR 48775, Aug. 11, 2004; 72 FR 58999, Oct. 18, 2007; 74 FR 13113, Mar. 26, 2009; 74 FR 37167, July 28, 2009]

§ 314.90 Waivers.

(a) An applicant may ask the Food and Drug Administration to waive under this section any requirement that applies to the applicant under §§ 314.50 through 314.81. An applicant may ask FDA to waive under § 314.126(c) any criteria of an adequate and well-controlled study described in § 314.126(b). A waiver request under this section is required to be submitted with supporting documentation in an application, or in an amendment or supplement to an application. The waiver request is required to contain one of the following:

(1) An explanation why the applicant's compliance with the requirement is unnecessary or cannot be achieved;

(2) A description of an alternative submission that satisfies the purpose of the requirement; or

(3) Other information justifying a waiver.

(b) FDA may grant a waiver if it finds one of the following:

(1) The applicant's compliance with the requirement is unnecessary for the agency to evaluate the application or compliance cannot be achieved;

(2) The applicant's alternative submission satisfies the requirement; or

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(3) The applicant's submission otherwise justifies a waiver.

[50 FR 7493, Feb. 22, 1985, as amended at 50 FR 21238, May 23, 1985; 67 FR 9586, Mar. 4, 2002]

§ 314.91 Obtaining a reduction in the discontinuance notification period.

(a) *What is the discontinuance notification period?* The discontinuance notification period is the 6-month period required under § 314.81(b)(3)(iii)(a). The discontinuance notification period begins when an applicant who is the sole manufacturer of certain products notifies FDA that it will discontinue manufacturing the product. The discontinuance notification period ends when manufacturing ceases.

(b) *When can FDA reduce the discontinuance notification period?* FDA can reduce the 6-month discontinuance notification period when it finds good cause exists for the reduction. FDA may find good cause exists based on information certified by an applicant in a request for a reduction of the discontinuance notification period. In limited circumstances, FDA may find good cause exists based on information already known to the agency. These circumstances can include the withdrawal of the drug from the market based upon formal FDA regulatory action (e.g., under the procedures described in § 314.150 for the publication of a notice of opportunity for a hearing describing the basis for the proposed withdrawal of a drug from the market) or resulting from the applicant's consultations with the agency.

(c) *How can an applicant request a reduction in the discontinuance notification period?* (1) The applicant must certify in a written request that, in its opinion and to the best of its knowledge, good cause exists for the reduction. The applicant must submit the following certification:

The undersigned certifies that good cause exists for a reduction in the 6-month notification period required in § 314.81(b)(3)(iii)(a) for discontinuing the manufacture of (*name of the drug product*). The following circumstances establish good cause (*one or more of the circumstances in paragraph (d) of this section*).

(2) The certification must be signed by the applicant or the applicant's attorney, agent (representative), or other